DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 2 1991

Re: Dekantel Microflex
Ophthalmic Suture
Docket No. 91E-0091

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U. S. Patent No. 4,621,638 filed by Pfizer Hospital Products Group, Inc., under 35 U.S.C 156. The medical device claimed by the patent is the Dekantel Microflex Ophthalmic Suture.

A review of the Food and Drug Administration's official records does not confirm that the Dekantel Microflex Ophthalmic Suture was subject to a regulatory review period as it is defined in 35 U.S.C. 156. For medical devices, section 156(g)(3) limits the meaning of the term "regulatory review period," to periods of time related to product approvals under section 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Dekantel Microflex Ophthalmic Suture was not approved under section 515, but instead received permission to market under section 510(k)of the FFDCA.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

CC: John L. LaPierre
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